



PATENT

Client-Matter No.: 68911-018 (METAG.002A2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Babish et al.

Serial No.: 09/919,506

Filed: July 31, 2001

For: COMBINATIONS OF
SESQUITERPENE LACTONES AND
DITERPENE LACTONES OR
TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

) Confirmation No: 2768

) Examiner: P. Patten

) Group Art Unit: 1654

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Sir:

I, John G. Babish, declare as follows:

1) I am the John G. Babish who is named as an inventor on the above-identified patent application.

2) I understand that the claims stand rejected, in part, as allegedly anticipated by Yng-Wong, U.S. Patent No. 5,874,084.

3) The Office Action indicates that Yng-Wong describes a composition containing *Saussurea lappa* (costus root) and *Glycyrrhizae glabra* (licorice root). However, the herbal formula disclosed by Yng-Wong in which these herbs are used in combination (Formula II) consists of a 1:1 extract using a solvent described as about 95% SDA 3C and about 5% water. SDA 3C is further described as 95% ethanol and 5% isopropyl alcohol.

4) Sesquiterpene lactones and triterpenes are insoluble in water or polar alcohols, generally requiring combinations of nonpolar solvents such as chloroform and ether when

Inventors: Babish et al.
Serial No.: 09/919,506
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Page 2

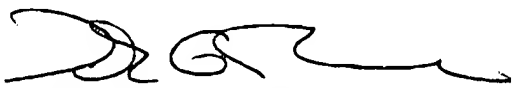
alcohols are used. Further, optimal solvents for sesquiterpene lactones are suboptimal for triterpenes. Thus, given the extraction method described in Yng-Wong, it is unlikely that the formulation taught by Yng-Wong contains either "an effective amount" of sesquiterpene lactones or "an effective amount" of triterpenes and even less likely that it contains "effective amounts" of both. In addition, the solvent containing 95% SDA 3C and 5% water would extract very few vitamins and no minerals, fats or proteins.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date:

12/3/03

By:



John G. Babish